DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 1, 2015

Fujifilm Medical System U.S.A., Inc.
Mary Moore
Senior Director, Regulatory Affairs and Quality Assurance
10 High Point Drive
Wayne, NJ 07470

Re: K150221
Trade/Device Name: EPX-4440HD and EPX-4400 HD with FICE
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET, GCT
Dated: August 19, 2015
Received: August 19, 2015

Dear Mary Moore,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150221

Device Name
EPX-4400 and EPX-4400 HD with FICE

Indications for Use *(Describe)*

The EPX-4400 and EPX-4400HD Digital Video Processors with FICE are used for endoscopic observation, diagnosis, treatment, and image recording. The devices are intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope). The devices may be used on all patients requiring endoscopic examination and when using a Fujinon/FUJIFILM medical endoscope, light source, monitor, recorder and various peripheral devices. FICE is an adjunctive tool for gastrointestinal endoscopic examination which can be used to supplement FUJIFILM white light endoscopy. FICE is not intended to replace histopathological sampling as a means of diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

FUJIFILM Medical Systems U.S.A., Inc.'s EPX-4400 and EPX-4400 HD with FICE

Submitter's Information:
FUJIFILM Medical Systems U.S.A., Inc., Endoscopy Division
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Persons:
Mary K. Moore
Senior Director, Regulatory Affairs and Quality Assurance
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Facsimile: (973) 686-2616
E-Mail: mkmoore@fujifilm.com

Date Prepared: January 30, 2015

Identification of the Proposed Device:
Proprietary/Trade Name: FUJIFILM EPX-4440HD and EPX-4400 HD with FICE
Common Name: Endoscopic Video Processor

Classification Information:

Classification Name	CFR Section	Product Code
Endoscopic Video Imaging System/ Component, Gastroenterology-Urology	21 CFR 876.1500	FET, GCT

Predicate Devices

FUJIFILM Medical Systems U.S.A., Inc.'s EPX-4440 HD Digital Video Processor with FICE (K140149)

Intended Use / Indications for Use

The EPX-4400 and EPX-4400HD Digital Video Processors with FICE are used for endoscopic observation, diagnosis, treatment, and image recording. The devices are intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope). The devices may be used on all patients requiring endoscopic examination and when using a Fujinon/FUJIFILM medical endoscope, light source, monitor, recorder and various peripheral devices. FICE is an adjunctive tool for gastrointestinal endoscopic examination which can be used to supplement FUJIFILM white light endoscopy. FICE is not intended to replace histopathological sampling as a means of diagnosis.

Technological Characteristics

This subject device is intended to be used in conjunction with Fujinon/FUJIFILM endoscopes to provide illumination, visual display and data storage during endoscopic procedures. The EPX-4400 and EPX-4400HD Digital Video Processor with FICE and light source consist of three components used in conjunction with one another:

> The VP-4400/4400HD Video Processor: The Processor relays the image from the endoscope to a video monitor. Projection can be either analog or digital at the user's preference. The Processor incorporates internal or external digital storage capacity. The Processor also controls the light projected to the body cavity. The Processor provides for optional structural enhancement at the user's option. Spectral and structural enhancements are achieved through proprietary software.
>
> The XL-4400/4400HD Light Source: The Fujinon/FUJIFILM endoscope employs fiber bundles to transmit light from the light source and subsequently to the body cavity. The Light Source employs a 300W Xenon lamp with a 75W emergency back-up Halogen lamp. Brightness control is performed by the user.
>
> The DK-4400E Keyboard: The Keyboard is used to enter pertinent procedural information (patient, physician, date, etc.) for display on the video monitor and digital/analog storage systems. The Keyboard is also used to control operational features of the VP-4400/4400HD Processor.

Both EPX-4400 and EPX-4400HD contain FICE which is an image processing technology. A licensed medical practitioner (user) can utilize FICE, as an adjunctive tool, to supplement the white light endoscopic examination. FICE extracts spectral images of specific wavelength components from the original full spectral (white light) image through an image processing algorithm that, assigns a spectral wavelength component in the Red (R), Green (G) and Blue (B) spectrum and displays the enhanced color image. FICE may enhance color contrast to improve visibility of the selected structures, borders of areas of interests.

Performance Data

The EPX-4400/4440HD Digital Video Processor is non-sterile and has no potential for patient contact. Testing of the VP-44000/4400HD with FICE consisted of software validation in accordance with IEC 62304 and electrical safety in accordance with IEC 60601 requirements. FUJIFILM has performed the same testing that was used to fully characterize the FICE feature as part of clearance with use with the EPX-4440HD system in K140149. All predetermined testing criteria were met, and in all instances the device functioned as intended. These tests include:

1. Contrast Enhancement
2. Resolution
3. Noise
4. Artifact
5. Color Reproduction

EMC and electrical safety of the subject devices were evaluated using the following consensus standards: ANSI/AAMI ES60601-1:2005; IEC 60601-1-2:2007; IEC 60601-1-6:2010; and IEC 60601-2-18:2009.

Substantial Equivalence

The EPX-4400 and EPX-4400HD with FICE are as safe and effective as the EPX-4440HD Digital Video Processor with FICE. The EPX-4400 and EPX-4400HD with FICE have the same intended uses and similar indications, technological characteristics, and principles of operation as their predicate device. The minor technological differences between the EPX-4400 and EPX-4400HD with FICE and their predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the EPX-4400 and EPX-4400HD with FICE are as safe and effective as the EPX-4440HD Digital Video Processor with FICE. Thus, the EPX-4400/4000HD with FICE are substantially equivalent to EPX-4440HD with FICE.

Conclusions

The EPX-4400 and EPX-4400HD with FICE are substantially equivalent to similar legally marketed devices and conforms to applicable medical device safety and performance standards.